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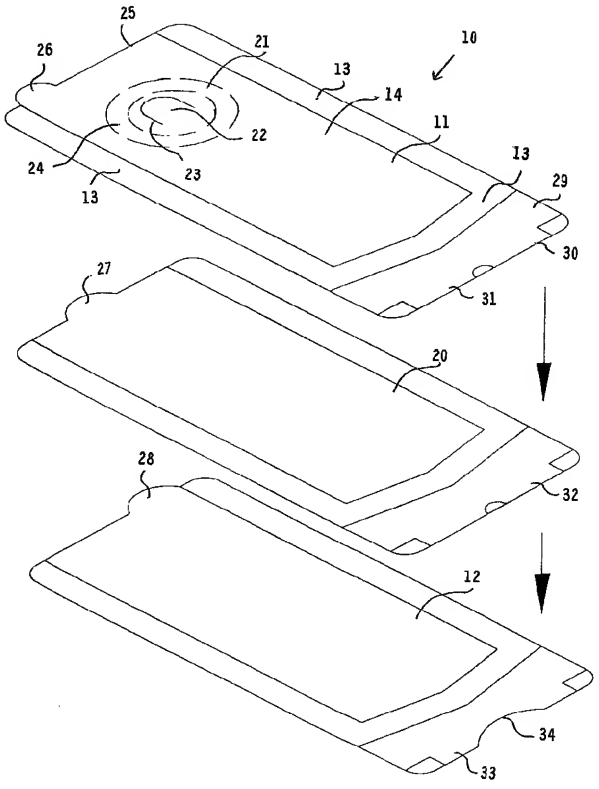
(54) Title: POUCH FOR PACKAGING A MEDICAL DEVICE




(57) Abstract: A pouch (10) for packaging a medical device to be sterilized by a gas sterilization process has a first surface (11) and a second surface (12), which are sealed together during assembly at the edges (13) to form an outer envelope (14) having a sealable opening (16) along one side (17) thereof for receiving the medical device in use. The pouch (10) is internally divided into a device receiving pocket (18) and a venting section (19) by a gas permeable microbe impermeable partition (20). An openable vent (21) is located in the first surface (11). This flap (22) curls in response to a raised temperature thus exposing an aperture (23) through which the sterilizing gas can enter the pouch (10). When the temperature returns to ambient the flap (22) flattens out and reseals the aperture (23). In use a medical device to be packaged is placed in the device receiving pocket (18) of the pouch (10) and a desiccant strip, if required, is placed in the venting section (19). The pouch (10) is then sealed along the edge (17) and is sterilized. An adhesive patch (not shown) can then be placed over the flap (22) to provide a watertight seal. As the pouch (10) is watertight, following sterilization, it does not have to be stored under aseptic or humidity controlled conditions.

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

Description

# POUCH FOR PACKAGING A MEDICAL DEVICE

## Technical Field

This invention relates to a pouch for packaging a medical device and, in particular, to a pouch for packaging an absorbable medical device to be sterilized by a gas sterilization process.

## Background Art

Certain types of medical devices, such as surgical sutures, are designed to absorb when placed in the human body. These sutures are made from absorbable polymers such as polyglycolic acid and are moisture sensitive. Thus, it is necessary to package such devices in moisture impervious packaging.

Absorbable medical devices are usually supplied in a sterile state and the sterilization method of choice is the use of ethylene oxide gas. One current packaging method for such medical devices is to double pack them. The product is first placed in a foil pouch and then the foil pouch is over-wrapped in a secondary pouch, which is constructed from either TYVEK (TYVEK is a trade mark of E.I. du Pont de Nemours and Company) or a surgical grade kraft paper with a transparent gas impervious lid. The outer pouch acts as a gas permeable microbe impermeable cover. The outer pouch is sealed leaving the inner foil pouch open to allow the sterilization gas to circulate and sterilize the product. Once the product has been sterilized, the product then rests and

degasses for a period of about five days before being returned to the manufacturer for sealing of the inner foil pouch. During this time the product can absorb water from the atmosphere. Upon return and prior to sealing the inner pouch, the package is placed in a vacuum oven and dried to below 0.2% water content. This process may take between 24-48 hours. The inner pouch is then sealed through the outer pouch.

Some manufacturers, sterilizing in-house, present their sutures for sterilizing in the foil pouch only. Once the product has been sterilized, the pouch is sealed under aseptic conditions, over-wrapped in a secondary pouch and re-sterilized.

It is difficult and costly to maintain aseptic conditions when a large volume of packages is being processed. Also moisture must be precisely controlled in the aseptic environment to prevent deterioration of absorbable medical devices.

U.S. Patent No. 5,868,244 describes a vented package for a sterile medical device, in which the package is divided into two compartments. One compartment contains the medical device to be sterilized and is sealed except for a channel joining it to the second compartment. The second compartment is in turn sealed except for a gas permeable, microbe impermeable vent. During the sterilization process the gas enters into the second compartment through the vent and passes into the first compartment through the connecting channel.

After sterilization the package may be stored in a humidity controlled storage area prior to further processing. The package is then

sealed across the connecting channel and the second compartment can be cut away.

Thus, although storage of the package following sterilization does not have to be in an aseptic environment, it must be humidity controlled.

It is an object of the present invention to overcome the disadvantages of the packages for medical devices as hereinbefore described.

Disclosure of Invention

Thus, the invention provides a pouch for packaging a medical device to be sterilized by a gas sterilization process, said pouch comprising a gas permeable microbe impermeable sealable pocket for receiving the medical device in use, the pocket being located within an outer gas impermeable sealable envelope, such that in use the medical device is placed within the pocket and sealed therein, and the sterilizing gas is then introduced into the outer envelope and from there circulates through the pocket to sterilize the medical device therein.

Since the pouch is divided into two sections, the sealable pocket and the outer envelope, the outer envelope section provides a transient area through which the sterilizing gas must pass in order to access and sterilize the medical device within the sealable pocket. Where the device is sensitive to moisture, such as a synthetic absorbable suture, a desiccant strip can be placed in the outer envelope, prior to sealing, and this prevents the suture from reabsorbing moisture post-sterilization.

Suitably, the pocket is made from spun, bonded, olefin material.

Alternatively, the pocket is made from surgical grade coated kraft paper.

In one embodiment of the pouch in accordance with the invention, the outer envelope is internally divided into the pocket and a venting section by a gas permeable microbe impermeable partition, which is attached to the inner surface of the outer envelope.

An advantage of forming the pocket from a gas permeable microbe impermeable partition is that the pouch can be assembled by sandwiching the partition between two outer layers of material forming the outer envelope.

Since the pouch is divided into the pocket and the venting section, the venting section provides a transient area through which the sterilizing gas must pass in order to access and sterilize the medical device. Where the device is sensitive to moisture, such as a synthetic absorbable suture, a desiccant strip can be placed in the venting section, prior to sealing, and this prevents the suture from reabsorbing moisture after sterilization.

Suitably, the outer envelope is made from medical packaging film.

Preferably, the medical packaging film is heat sealable.

Further, preferably, the medical packaging film is transparent.

It can be useful for one to be able to see through the outer envelope. Thus, a transparent film such as ClearFoil (ClearFoil is a trade mark of Rollprint Packaging Products, Inc.) can be used to form part or all of the outer envelope.

The use of heat-sealable film results in a rapid low cost method for assembling the pouches.

In a further embodiment of the pouch in accordance with the invention, the outer envelope has a vent on a surface thereof, through which the sterilizing gas is introduced in use.

The use of a vent allows the outer envelope to be sealed prior to the gas sterilization process.

Preferably, the vent is openable such that it moves between a closed state at ambient temperature and an open state at a raised temperature generated during the sterilization process.

The provision of an openable vent assists in preventing re-ingress of moisture after sterilization.

Suitably, the vent includes a layer of gas permeable microbe impermeable material through which the gas must pass in use.

The gas permeable microbe impermeable layer acts as a first microbial barrier for protecting the device. If this barrier is breached the gas permeable microbe impermeable pocket will still maintain the sterility of the device.

Preferably, the layer of gas permeable microbe impermeable material is attached to the inside surface of the outer envelope under the vent.

Further, preferably, the vent includes a layer of desiccant material through which the gas must pass in use.

Suitably, the vent is a flap cut in the outer envelope material, the flap in use curling in response to the raised temperature generated during the sterilization process to uncover an aperture through which the sterilizing gas can enter the pouch.

A flap which is sensitive to temperature changes provides a simple method for opening and closing the vent. The flap operates in accordance with natural mechanical laws of expansion and contraction.

Preferably, the temperature at which the flap curls is in the range of 30°- 50° C.

Suitably, the pouch has an adhesive patch for sealing the vent following the sterilizing process.

Suitably, the or each section has an identifying tab associated therewith.

Having identifying tabs for the sections speeds up the packaging process and minimises the risk of placing the device in the incorrect section.

Advantageously, the pouch has an adhesive patch for sealing the vent following the sterilizing process.

Although the vent minimises the risk of moisture entering the pouch following the sterilization process, the addition of an adhesive patch provides a watertight seal and ensures that no moisture can enter through the vent. Thus, the pouch does not have to be stored under aseptic or humidity controlled conditions.

The invention will be further illustrated by the following description of an embodiment thereof, given by way of example only with reference to the accompanying drawings.

Brief Description of Drawings

Fig. 1 is a perspective view of a pouch according to the invention;

Fig. 2 is an exploded view of the pouch of Fig. 1;

Fig. 3 is a cross-section on line III - III of Fig. 1, with the vent in the closed position; and

Fig. 4 is the cross-section of Fig. 3, but with the vent in the open position.

Best Mode for Carrying Out the Invention

Referring to Fig. 1 there is illustrated generally at 10, a pouch for packaging a medical device to be sterilised by a gas sterilization process,

having a first surface 11 and a second surface 12, which are sealed together during assembly at edges 13, to form an outer envelope 14 having a sealable opening 16 along one side 17 thereof for receiving the medical device in use. The pouch 10 is internally divided into a gas permeable microbe impermeable pocket 18 and a venting section 19 by a gas permeable microbe impermeable partition 20. An openable vent 21 is located in the first surface 11 and is in communication with the venting section 19. The vent 21 in use moves between a closed state at ambient temperature and an open state at a raised temperature generated during the sterilization process, thus allowing passage of a sterilizing gas into the venting section 19 and from there to the device receiving pocket 18 via the partition 20. The vent 21 has a flap 22, which is cut in the first surface 11. This flap 22 curls in response to a raised temperature thus exposing an aperture 23 through which the sterilizing gas can enter the pouch 10. When the temperature returns to ambient the flap 22 flattens out and reseals the aperture 23.

A layer of gas permeable microbe impermeable material 24 (ghost outline) is attached to inside surface 25 of the first surface 11 so as to cover the aperture 23.

Tabs 26,27,28 on the first surface 11, the partition 20 and the second surface 12, respectively, permit positive identification of the device receiving pocket 18 and the venting section 19.

A flattened area 29 at an end 30 of the pouch 10 is used for opening the pouch by the user of the device contained therein.

In use a medical device to be packaged is placed in the device receiving pocket 18 of the pouch 10 and a desiccant strip, if required, is placed in the venting section 19. The pouch 10 is then sealed along the edge 17 and the pouch is sterilized using an ethylene oxide gas sterilizing procedure. During the sterilizing process the flap 22 opens to permit the sterilizing gas to circulate around the device. Following sterilization the pouch 10 is allowed to return to ambient temperature and the flap reseals the aperture 23. An adhesive patch (not shown) can then be placed over the flap 22 to provide a watertight seal.

The first surface 11 and the second surface 12 are made from a non-permeable heat sealable medical packaging film such as PerfecFlex EZ Peel film (PerfecFlex 35786-G High Barrier EZ Peel film), (PerfecFlex and EZ Peel are trade marks of Perfecseal, Inc.). The gas permeable microbe impermeable partition 20 and the layer of gas permeable microbe material 24 are made from TYVEK material (CR27 1073B all over coated TYVEK) (TYVEK is a trade mark).

Referring to Fig. 2, there is illustrated the pouch of Fig. 1 in an exploded view. The pouch 10 is made up from three layers, the first surface 11, the second surface 12 and the gas permeable microbe impermeable partition 20, sandwiched therebetween. The three layers are joined together by heat sealing.

Ends 31,32,33 of first surface 11, partition 20, and second surface 12 are joined together to form the flattened area 29 of the assembled pouch. A curved section 34 in end 33 facilitates the opening of the pouch 10 when the device contained therein is required, as the first

surface 11 and the partition 20 can be gripped by the user and peeled away from the second surface 12.

Referring to Figs. 3 and 4 the pouch 10 is illustrated containing a medical device 35 in the device receiving pocket 18 and a desiccant strip 36 in the venting section 19. The arrows in Fig. 4 indicate the circulation of sterilizing gas through the aperture 23, around the venting section 19, through the partition 20 and around the medical device 35 in the device receiving pocket 18.

Claims: -

1. A pouch for packaging a medical device to be sterilized by a gas sterilization process, said pouch comprising a gas permeable microbe impermeable sealable pocket for receiving the medical device in use, the pocket being located within an outer gas impermeable sealable envelope, such that in use the medical device is placed within the pocket and sealed therein, and the sterilizing gas is then introduced into the outer envelope and from there circulates through the pocket to sterilize the medical device therein.

2. A pouch according to Claim 1, wherein the pocket is made from spun, bonded, olefin material.

3. A pouch according to Claim 1, wherein the pocket is made from surgical grade coated kraft paper.

4. A pouch according to Claim 1 or 2, wherein the outer envelope is internally divided into the pocket and a venting section by a gas permeable microbe impermeable partition, which is attached to the inner surface of the outer envelope.

5. A pouch according to any preceding claim, wherein the outer envelope is made from medical packaging film.

6. A pouch according to Claim 5, wherein the medical packaging film is heat sealable.

7. A pouch according to Claim 5 or 6, wherein the medical packaging film is transparent.

8. A pouch according to any preceding claim, wherein the outer envelope has a vent on a surface thereof, through which the sterilizing gas is introduced in use.

9. A pouch according to Claim 8, wherein the vent is openable such that it moves between a closed state at ambient temperature and an open state at a raised temperature generated during the sterilization process.

10. A pouch according to Claim 8 or 9, wherein the vent includes a layer of gas permeable microbe impermeable material through which the gas must pass in use.

11. A pouch according to Claim 10, wherein the layer of gas permeable microbe impermeable material is attached to the inside surface of the outer envelope under the vent.

12. A pouch according to any one of Claims 8-11 wherein the vent includes a layer of desiccant material through which the gas must pass in use.

13. A pouch according to any one of Claims 8-12, wherein the vent is a flap cut in the outer envelope material, the flap in use curling in response to the raised temperature generated during the sterilization process to uncover an aperture through which the sterilizing gas can enter the pouch.

14. A pouch according to Claim 13, wherein the temperature at which the flap curls is in the range of 30°- 50° C.

15. A pouch according to any one of Claims 8-14, having an adhesive patch for sealing the vent following the sterilizing process.

16. A pouch according to Claim 1, for packaging a medical device to be sterilized by a gas sterilization process, substantially as hereinbefore described with particular reference to and as illustrated in the accompanying drawings.

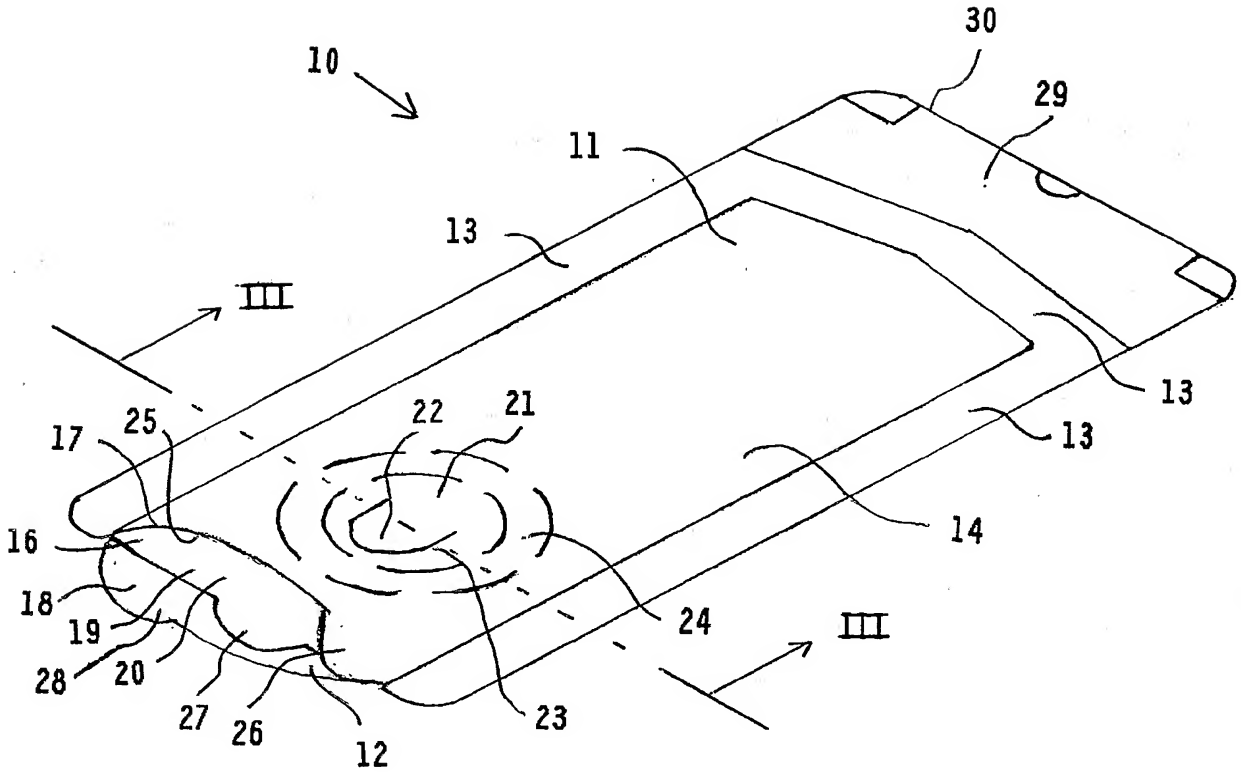
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Fig. 1

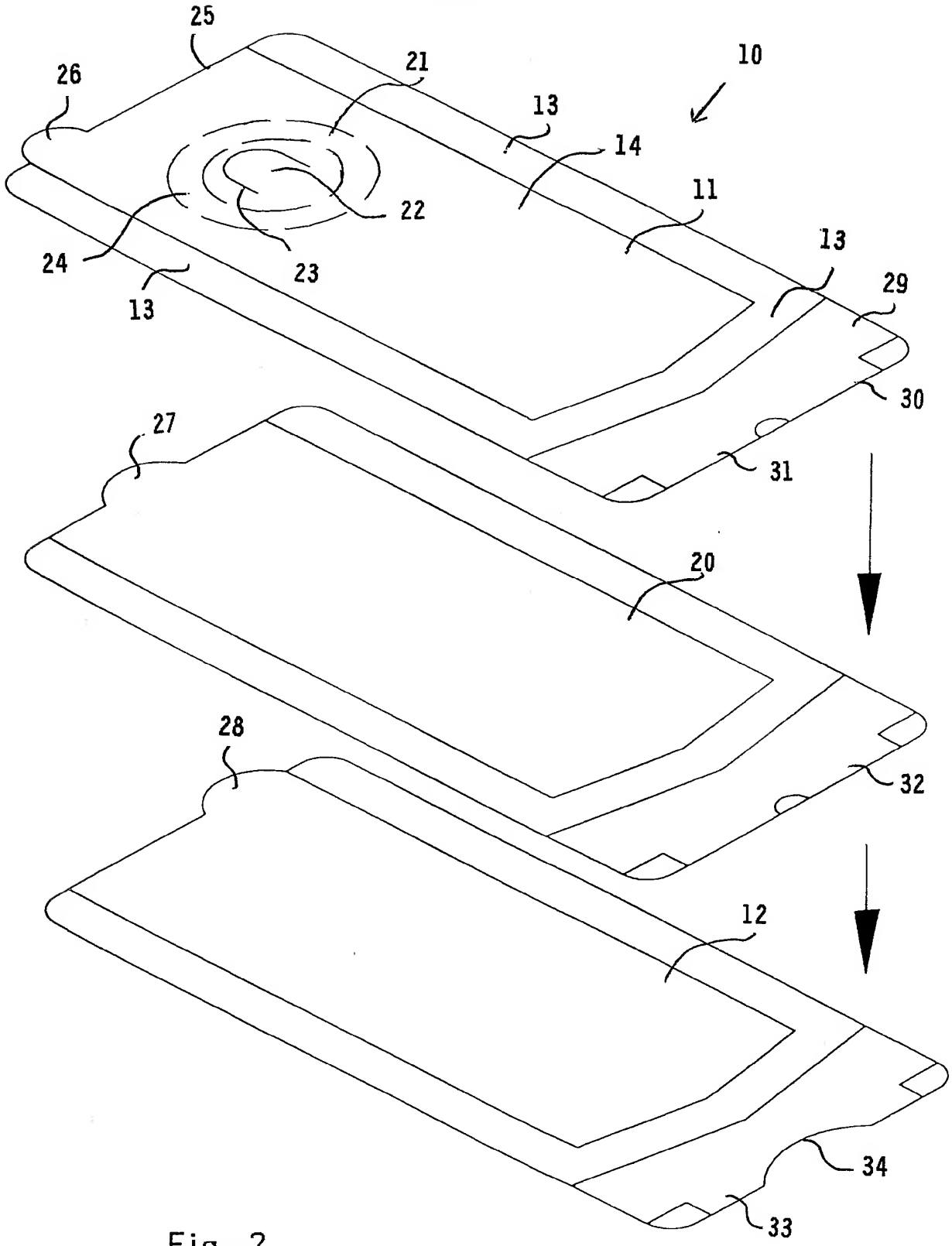


Fig. 2

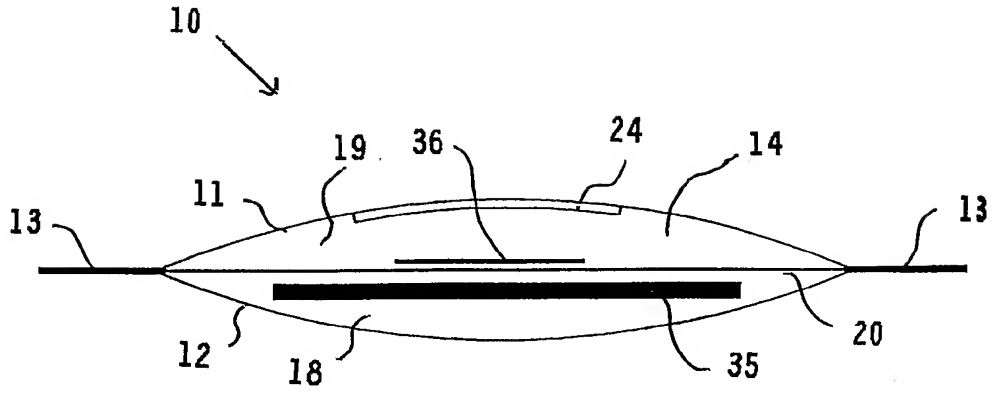
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Fig. 3

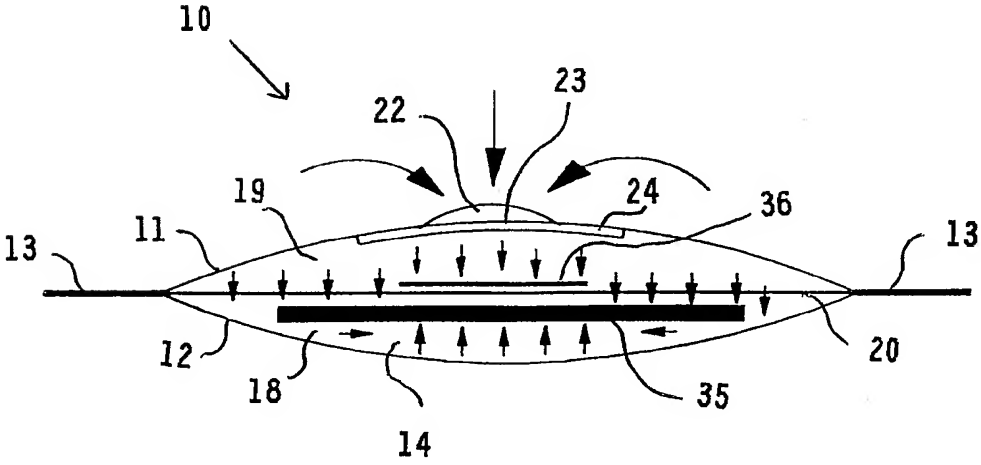
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Fig. 4

# INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 03/00021

**A. CLASSIFICATION OF SUBJECT MATTER**
IPC 7 A61B17/06 A61L2/20 A61L2/26

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 4 714 595 A (ANTHONY JACK ET AL)<br>22 December 1987 (1987-12-22) | 1-3,8 |
| A | column 1, line 36 - line 58<br>column 2, line 5 - line 32<br>column 3, line 37 - line 55<br>column 5, line 3 -column 6, line 66;<br>figures 1-9 | 7 |
| X | US 4 777 780 A (HOLZWARTH HENRY A)<br>18 October 1988 (1988-10-18)<br>column 2, line 3 - line 49<br>column 3, line 11 -column 4, line 20;<br>figures 1-4 | 1,2,5-7 |
| X | GB 2 077 592 A (GEISTLICH SOEHNE AG)<br>23 December 1981 (1981-12-23)<br>page 1, line 68 - line 87<br>page 2, line 5 - line 15 | 1,2,5,6 |

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 26 September 2003 | 07/10/2003 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Grondin, D |

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# INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 03/00021

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication,where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 3 468 471 A (LINDER FRITZ)<br>23 September 1969 (1969-09-23)<br>column 1, line 58 -column 2, line 50;<br>figures 1,2 | 1,8,10,<br>11 |
| A | US 3 247 957 A (KEMBLE MERN S)<br>26 April 1966 (1966-04-26)<br>column 2, line 33 - line 52; figures 1-6 | 1,8,15 |
| A | US 3 939 971 A (TULIS JERRY J)<br>24 February 1976 (1976-02-24)<br>column 1, line 53 -column 3, line 29;<br>figures 1-4 | 1,4 |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/IE 03/00021

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 16
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 6.2(a) PCT

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Internal Application No
PCT/IE 03/00021

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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